

104TH CONGRESS
1ST SESSION

S. 333

To direct the Secretary of Energy to institute certain procedures in the performance of risk assessments in connection with environmental restoration activities, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 2 (legislative day, JANUARY 30), 1995

Mr. MURKOWSKI (for himself, Mr. JOHNSTON, and Mr. LOTT) introduced the following bill; which was read twice and referred to the Committee on Energy and Natural Resources

A BILL

To direct the Secretary of Energy to institute certain procedures in the performance of risk assessments in connection with environmental restoration activities, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION. 1. SHORT TITLE.**

4 This Act may be cited as the “Department of Energy
5 Risk Management Act of 1995.”

6 **SEC. 2. TABLE OF CONTENTS.**

Sec. 1. Short title.
Sec. 2. Table of contents.
Sec. 3. Definitions.

- Sec. 4. Applicability; principles for risk assessment, characterization and communication.
- Sec. 5. Regulation; plan for assessing new information.
- Sec. 6. Requirements for environmental restoration activity.
- Sec. 7. Environmental restoration priorities.
- Sec. 8. Judicial review.
- Sec. 9. Savings provisions.

1 **SEC. 3. DEFINITIONS.**

2 In this Act:

3 (1) **BEST ESTIMATE.**—The term “best esti-
 4 mate” means an estimate that, to the extent feasible
 5 and scientifically appropriate, provides the most un-
 6 biased representation of the most plausible level of
 7 risk, given the most reliable current scientific infor-
 8 mation available to the Department.

9 (2) **COSTS.**—The term “costs” includes the di-
 10 rect and indirect costs to the United States Govern-
 11 ment, to State and local governments, and to the
 12 private sector, of implementing and complying with
 13 a regulatory action.

14 (3) **DEPARTMENT.**—The term “Department”
 15 means the Department of Energy.

16 (4) **ENVIRONMENTAL RESTORATION ACTIV-**
 17 **ITY.**—The term “environmental restoration activity”
 18 means a removal or remedial action conducted by
 19 the Department at nuclear facilities under the con-
 20 trol of the Department, including the Savannah
 21 River Site, Hanford Nuclear Reservation, Nevada
 22 Test Site, Rocky Flats Plant, Idaho National Engi-

neering Laboratory, Los Alamos National Laboratory, Lawrence Livermore National Laboratory, and any other such facility.

(5) HAZARD.—The term “hazard” means a substance, activity, or condition which potentially poses a risk to human health or safety or the environment based on empirical data, measurements, or testing showing that it has caused significant adverse effects at some levels of dose or exposure not necessarily relevant to level of dose or exposure that are normally expected to occur.

(6) PLAUSIBLE.—The term “plausible” means realistic and scientifically probable.

(7) RISK ASSESSMENT.—The term “risk assessment” means—

(A) the process of identifying hazards and quantifying or describing the degree of toxicity, exposure, or other risk they pose for demonstrably exposed individuals, populations, or resources; or

(B) the document containing the explanation of how the risk assessment process has been applied to an individual substance, activity, or condition.

1 (8) RISK CHARACTERIZATION.—The term “risk
2 characterization”—

3 (A) means the element of a risk assess-
4 ment that involves presentation of the degree of
5 risk set forth in any plan, assessment, or record
6 of decision, report to Congress, or other docu-
7 ment that is made available to the public; and

8 (B) includes discussions of uncertainties,
9 conflicting data, estimates, extrapolations, in-
10 ferences, justifications, and opinions.

11 (9) SECRETARY.—The term “Secretary” means
12 the Secretary of Energy, or the Secretary’s designee.

13 (10) SUBSTITUTION RISK.—The term “substi-
14 tution risk” means a potential increased risk to
15 human health, safety, or the environment from a
16 regulatory option designed to decrease other risks.

17 **SEC. 4. APPLICABILITY; PRINCIPLES FOR RISK ASSESS-**
18 **MENT, RISK CHARACTERIZATION, AND COM-**
19 **MUNICATION.**

20 (a) APPLICABILITY.—

21 (1) IN GENERAL.—Except as provided in para-
22 graph (2), this Act applies to all risk assessments
23 and risk characterizations prepared by, or on behalf
24 of, the Department as part of an environmental res-
25 toration activity.

1 (2) EXCEPTIONS.—

2 (A) EMERGENCIES AND SCREENING ANAL-
3 YSES.—This Act does not apply to risk assess-
4 ments or risk characterizations performed with
5 respect to either of the following:

6 (i) A situation that the Secretary de-
7 termines to be an emergency.

8 (ii) A screening analysis, including a
9 screening analysis for purposes of product
10 regulation, product reregistration, or
11 premanufacturing notices.

12 (B) TREATMENT OF ANALYSIS AS SCREEN-
13 ING ANALYSIS.—No analysis shall be treated as
14 a screening analysis for purposes of subpara-
15 graph (A) if the results of the analysis is
16 used—

17 (i) as the basis for imposing restrictions on
18 substances or activities; or

19 (ii) to characterize a positive finding of
20 risks from substances or activities in any De-
21 partmental document made available to the gen-
22 eral public.

23 (b) PRINCIPLES FOR RISK ASSESSMENT.—

24 (1) IN GENERAL.—The Secretary shall apply
25 the principles set forth in paragraph (2) when pre-

1 paring a risk assessment in order to ensure that the
2 risk assessment distinguishes scientific findings from
3 other considerations and are, to the maximum extent
4 feasible, scientifically objective, unbiased, and inclu-
5 sive of all relevant data. Discussions or explanations
6 required under this section need not be repeated in
7 each risk assessment document as long as there is
8 a reference to the relevant discussion or explanation
9 in another agency document.

10 (2) PRINCIPLES.—The principles to be applied
11 when preparing risk assessments are as follows:

12 (A) HUMAN HEALTH RISKS.—When as-
13 sessing human health risks in connection with
14 a risk assessment, the Secretary shall consider
15 and discuss both laboratory and epidemiological
16 data of sufficient quality that finds, or fails to
17 find, a correlation between health risks and a
18 potential toxin or activity. When conflicts
19 among the data appear to exist or when animal
20 data are used as a basis to assess human
21 health, the assessment shall include discussion
22 of possible reconciliation of conflicting data.

23 (B) SIGNIFICANT ASSUMPTIONS.—When a
24 risk assessment involves selection of any signifi-

1 cant assumption, inference, or model, the Sec-
2 retary shall—

3 (i) describe the plausible alternative
4 assumptions, inferences, or models;

5 (ii) explain the basis for any choices
6 among the assumptions, inferences, or
7 models;

8 (iii) identify any policy or value judg-
9 ments involved in choosing from among the
10 alternative assumptions, inferences, or
11 models;

12 (iv) fully describe any model used in
13 the risk assessment and make explicit the
14 assumptions incorporated in the model;
15 and

16 (v) indicate the extent to which any
17 significant model has been validated by, or
18 conflicts with, empirical data.

19 (c) PRINCIPLES FOR RISK CHARACTERIZATION AND
20 COMMUNICATION.—When characterizing risk, the Sec-
21 retary shall comply with each of the following:

22 (1) ESTIMATES OF RISK.—

23 (A) BEST ESTIMATE.—The Secretary shall
24 describe the populations or natural resources
25 that are the subject of the risk characterization.

1 If a numerical estimate of risk is provided, the
2 Secretary shall, to the extent feasible and sci-
3 entifically appropriate, provide—

4 (i) the best estimate for the specific
5 populations or natural resources that are
6 the subject of the characterization (based
7 on the information available to the Depart-
8 ment); and

9 (ii) a statement of the reasonable
10 range of scientific uncertainties.

11 (B) MULTIPLE BEST ESTIMATES.—In ap-
12 propriate circumstances the Secretary may
13 present, in lieu of a single best estimate, mul-
14 tiple estimates based on assumptions, infer-
15 ences, or models that are equally plausible,
16 given current scientific understanding.

17 (C) PLAUSIBLE UPPER-BOUND OR CON-
18 SERVATIVE ESTIMATES.—In addition to a best
19 estimate or estimates, the Secretary may
20 present plausible upper-bound or conservative
21 estimates in conjunction with plausible lower
22 bounds estimates.

23 (D) DESCRIPTIONS OF DISTRIBUTION AND
24 PROBABILITY.—To the extent practicable and
25 appropriate, the Secretary shall provide descrip-

1 tions of the distribution and probability of risk
2 estimates to reflect differences in exposure vari-
3 ability in populations and uncertainties.

4 (2) EXPOSURE SCENARIOS.—The Secretary
5 shall explain the exposure scenarios used in any risk
6 assessment, and, to the extent feasible, provide a
7 statement of the size of the corresponding popu-
8 lation at risk and the likelihood of the exposure sce-
9 narios.

10 (3) COMPARISONS.—To the extent feasible, the
11 Secretary shall provide a statement that places the
12 nature and magnitude of risks to human health in
13 context. The statement shall include appropriate
14 comparisons with estimates of risks that are familiar
15 to and routinely encountered by the general public
16 as well as other risks.

17 (4) SUBSTITUTION RISKS.—When the Secretary
18 provides a risk assessment or risk characterization
19 for an environmental restoration activity, the assess-
20 ment or characterization shall include a statement of
21 any significant substitution risks to human health,
22 where information on such risks has been provided
23 to the Secretary.

1 **SEC. 5. REGULATION; PLAN FOR ASSESSING NEW INFORMA-**
2 **TION.**

3 (a) REGULATION.—Within 1 year after the date of
4 enactment of this Act, the Secretary shall issue a final
5 regulation implementing for the Department the risk as-
6 sessment and risk characterization principles set forth in
7 this Act. The final regulation shall establish a format for
8 summarizing risk assessment results.

9 (b) PLAN.—

10 (1) IN GENERAL.—Within 1 year after the date
11 of enactment of this Act, the Secretary shall promul-
12 gate a plan to review and revise any risk assessment
13 prepared by or on behalf of the Secretary and com-
14 pleted prior to the promulgation of the plan, if the
15 Secretary determines that significant new informa-
16 tion or methodologies are available that could signifi-
17 cantly alter the results of the prior risk assessment
18 or that there are other appropriate reasons why such
19 a review and revision should be conducted.

20 (2) CONTENTS.—A plan promulgated under (1)
21 shall—

22 (A) provide procedures for receiving and
23 considering new information and risk assess-
24 ments from the public;

1 (B) set priorities for review and revision of
2 risk assessments based on such factors as the
3 Secretary considers appropriate; and

4 (C) include a process by which members of
5 the public may petition the Secretary for review
6 of particular assessments.

7 (3) RESPONSE TO PETITION.—Not later than
8 60 days after receiving a petition under paragraph
9 (2)(C), the Secretary shall respond to the petition by
10 agreeing or declining to review the risk assessment
11 referred to in the petition, and shall state the basis
12 for the decision.

13 (4) COMPLETION OF REVIEW.—If the Secretary
14 agrees to review a risk assessment, the Department
15 shall complete its review within 180 days, unless the
16 Secretary agrees in writing that an extension not to
17 exceed 60 days is necessary in view of limitations on
18 Department resources.

19 (c) PUBLIC COMMENT AND CONSULTATION.—The
20 regulation and plan, under this sections shall be developed
21 after notice and opportunity for public comment.

22 (d) REVIEW.—At least every 4 years, the Secretary
23 shall review, and when appropriate, revise the regulation
24 and plan published under this section.

1 **SEC. 6. REQUIREMENTS FOR ENVIRONMENTAL RESTORA-**
2 **TION ACTIVITY.**

3 (a) IN GENERAL.—Any plan, assessment, or record
4 of decision to conduct an environmental restoration activ-
5 ity shall include a clear and concise statement that—

6 (1) describes and, to the extent practicable,
7 quantifies the risks to human health, safety, and the
8 environment to be addressed by the environmental
9 restoration activity;

10 (2) compares the human health or environ-
11 mental risks to be addressed by the environmental
12 restoration activity to other risks chosen by the Sec-
13 retary, including—

14 (A) at least 3 other risks regulated by the
15 Department or another Federal agency; and

16 (B) at least 3 other risks that are familiar
17 to the general public;

18 (3) describes and, to the extent practicable,
19 quantifies any known, plausible substitution risks
20 when information on such risks has been provided to
21 the Department;

22 (4) estimates—

23 (A) the costs to the United States Govern-
24 ment of conducting the environmental restora-
25 tion activity; and

1 (B) the benefits of the environmental res-
2 toration activity, including both quantifiable
3 measures of costs and benefits, to the fullest ex-
4 tent that they can be estimated, and qualitative
5 measures that are difficult to quantify; and

6 (5) contains a certification by the Secretary
7 that—

8 (A) the analyses performed under para-
9 graphs (1), (2), and (3) are, to the maximum
10 extent practicable—

11 (i) based on the best reasonably ob-
12 tainable scientific and economic informa-
13 tion; and

14 (ii) objective and unbiased;

15 (B) the environmental restoration activity
16 is likely to significantly reduce the human
17 health, safety, or environmental risks to be ad-
18 dressed;

19 (C) no environmental restoration activity
20 alternative that would achieve an equivalent re-
21 duction in risk in a more cost-effective manner
22 is permitted under the Comprehensive Environ-
23 mental Response, Compensation, and Liability
24 Act of 1980 (42 U.S.C. 9601 et seq.); and

1 (D) the environmental restoration activity
2 is likely to produce benefits to human health or
3 the environment that will justify the costs to
4 the United States Government.

5 (b) REPORTING.—If the Secretary cannot make a
6 certification with respect to 1 or more of the matters de-
7 scribed in subsection (a), the Secretary shall identify the
8 matters for which certification cannot be made, and shall
9 include a statement of the reasons why the certification
10 cannot be made in the plan, assessment, or record of deci-
11 sion. Not later than March 1 of each year, the Secretary
12 shall submit a report to Congress identifying the environ-
13 mental restoration activities conducted during the previous
14 calendar year for which complete certification was not
15 made, and summarizing the reasons therefore.

16 **SEC. 7. ENVIRONMENTAL RESTORATION PRIORITIES.**

17 (a) SETTING OF PRIORITIES.—The Secretary shall
18 prioritize the use of the resources available to conduct res-
19 toration activities to address the risks to human health,
20 safety and the environment that—

- 21 (1) the Secretary determines are the most seri-
22 ous; and
23 (2) can be addressed in a cost-effective manner,
24 with the goal of achieving the greatest overall net re-

1 duction in risks with the public and private sector
2 resources to be expended.

3 (b) DETERMINING MOST SERIOUS RISKS.—In identi-
4 fying the sources of the most serious risks under sub-
5 section (a), the Secretary shall consider, at a minimum—

6 (1) the plausible likelihood and severity of the
7 effect; and

8 (2) the plausible number and groups of individ-
9 uals potentially affected.

10 (c) INCORPORATION OF RISK-BASED PRIORITIES
11 INTO BUDGET AND PLANNING.—The Secretary shall in-
12 corporate the priorities identified in subsection (a) into the
13 Department’s budget, strategic planning, and research ac-
14 tivities by—

15 (1) in the Department’s annual budget request
16 to Congress—

17 (A) identifying which risks that the Sec-
18 retary has determined are the most serious and
19 can be addressed in a cost-effective manner
20 under subsection (a), and the basis for that de-
21 termination;

22 (B) explicitly identifying how the Depart-
23 ment’s requested funds will be used to address
24 those risks; and

1 (C) identifying any statutory, regulatory,
2 or administrative obstacles to allocating Depart-
3 mental resources in accordance with the prior-
4 ities established under subsection (a); and

5 (D) explicitly considering the requirements
6 of subsection (a) when preparing the Depart-
7 ment's environmental management plan or
8 other strategic plan and providing an expla-
9 nation of how the agenda or plan reflects those
10 requirements and the comparative risk analysis
11 when publishing any such agenda or strategic
12 plan.

13 (e) RECOMMENDATION.—In March of each year, the
14 Secretary shall submit to Congress specific recommenda-
15 tions for repealing or modifying laws that would better en-
16 able the Department to prioritize its activities to address
17 the risks to human health, safety, and the environment
18 that are the most serious and can be addressed in a cost-
19 effective manner consistent with the requirements of
20 subsection (a).

21 **SEC. 9. SAVINGS PROVISIONS.**

22 Nothing in this Act shall be construed to—

23 (1) modify any statutory standard or require-
24 ment designed to protect health, safety, or the envi-
25 ronment;

- 1 (2) preclude the consideration of any data or
2 the calculation of any estimate to more fully describe
3 risk or provide examples of scientific uncertainty or
4 variability; or
5 (3) require the disclosure of any trade secret or
6 other proprietary information.



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